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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,019	02/07/2001	Mark William Doane	0100/0090	6226
21395	7590	05/18/2004	EXAMINER	
LOUIS WOO LAW OFFICE OF LOUIS WOO 717 NORTH FAYETTE STREET ALEXANDRIA, VA 22314			MITCHELL, TEENA KAY	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/778,019

Applicant(s)

DOANE ET AL.

Examiner

Teena Mitchell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/19/04 (RCE).
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-9,12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) 8,9 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6,7,13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 February 2001 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/19/04 has been entered.

Oath/Declaration

The Oath/Declaration has been received and entered into the application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined

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under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 6, and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Brain (6,705,318).

Brain in a mask discloses:

- a soft cuff member (430), said cuff member having a substantially hollow annular shape;
- a rigid mount member (410), said mount member being more rigid than said cuff member and being of generally funnel shape,
- wherein said cuff member is a pre-formed component separate from said mount member, wherein said cuff member is formed by rotational moulding (Col. 7, lines 19-32), and wherein the mask includes a rotationally-moulded bond between said mount member and said cuff member. While Brain does not specifically state that the mask includes a rotationally-moulded bond between said mount member and said cuff member it would be inherent that such bond would exist, inasmuch as the device is made by rotational moulding. Furthermore it is still the examiner's position that the rotational moulding is the process and inasmuch so would be the rotationally-moulded bond. While the examiner has made an art rejection disclosing rotational moulding, the examiner still maintains the claim is a product-by-process claim and the

rotationally-moulded bond between the mount member and cuff member is also a part of the process of making the mask device.

With respect to claim 6, Brain discloses wherein the mask is a laryngeal mask (note all the figures and title of the invention "DISPOSABLE LMA) and said cuff member (430) is adapted to seal with tissue in the region of the hypopharynx (Col. 2, lines 29-63), it is also inherent and well-known in the respiratory art that a laryngeal mask cuff is adapted to seal with tissue in the region of the hypopharynx providing the needed seal.

With respect to claim 13, Brain discloses a soft cuff member (430), said cuff member being of substantially annular shape; a pre-formed rigid mount member (410), said mount member being more rigid than said cuff member and being of generally funnel shape, and wherein said cuff member is by rotational moulding (Col. 7, lines 19-32), and wherein the mask includes a rotationally-moulded bond between said mount member and said cuff member. While Brain does not specifically state that the mask includes a rotationally-moulded bond between said mount member and said cuff member it would be inherent that such bond would exist, inasmuch as the device is made by rotational moulding. Furthermore it is still the examiner's position that the rotational moulding is the process and inasmuch so would be the rotationally-moulded bond. While the examiner has made an art rejection disclosing rotational moulding, the examiner still maintains the claim is a product-by-process claim and the rotationally-moulded bond between the mount member and cuff member is also a part of the process of making the mask device.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brain (6,705,318) in view of Sullivan (5,243,971).

The difference between Brain and claim 7 is wherein said mask is a facemask.

Sullivan teaches a face mask (19) having a soft cuff member (13) and a mount member (24) molded with said mount member (Col. 2, lines 50-67) providing a self-conforming mask which by overlaying and conforming to the shape to the wearer provides an inherently large self-sealing area and can be used to seal around the nose and mouth of a user (Col. 2, lines 45-49 and Col. 4, lines 12-23).

It would be obvious to one of ordinary skill in the art at the time the invention was made to modify the laryngeal mask of Brain to employ any well-known face mask doing so would have provided a self-conforming mask which by overlaying and conforming to the shape to the wearer provides an inherently large self-sealing area and can be used to seal around the nose and mouth of a user including the face mask taught by Sullivan.

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Response to Arguments

Applicants arguments filed with the amendment in this RCE have been considered, however they are not persuasive because applicant contends that the rotational-moulding and rotationally-moulded bond are not product-by-process claims. The examiner maintains that such rotationally-moulding and rotationally-moulded bond (which is created by the rotational-moulding process, therefore is part of the process of making) limitations are part of a process and therefore not given patentable weight. However, the examiner in order to make the record clear has applied art that teaches rotational-moulded used in the manufacture of mask.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art is cited to show mask: 6,240,922; 6,021,779; 6,116,243.

If a copy of a provisional application listed on the bottom portion of the accompanying Notice of References Cited (PTO-892) form is not included with this Office action and the PTO-892 has been annotated to indicate that the copy was not readily available, it is because the copy could not be readily obtained when the Office action was mailed. Should applicant desire a copy of such a provisional application, applicant should promptly request the copy from the Office of Public Records (OPR) in accordance with 37 CFR 1.14(a)(1)(iv), paying the required fee under 37 CFR 1.19(b)(1). If a copy is ordered from OPR, the shortened statutory period for reply to this Office action will not be reset under MPEP § 710.06 unless applicant can

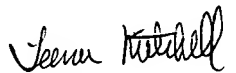
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demonstrate a substantial delay by the Office in fulfilling the order for the copy of the provisional application. Where the applicant has been notified on the PTO-892 that a copy of the provisional application is not readily available, the provision of MPEP § 707.05(a) that a copy of the cited reference will be automatically furnished without charge does not apply.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (703) 308-4016. The examiner can normally be reached on Monday-Friday during normal business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Teena Mitchell
Examiner
Art Unit 3743
May 13, 2004